IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re: Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Dkt. No. 20-1076-CFC
This Document Relates To: All End-Payor Class Actions	[redacted]

DECLARATION OF BENJAMIN M. GREENBLUM IN SUPPORT OF DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE THE MANUFACTURING AND COMMERCIAL LAUNCH OPINIONS OF JANET K. DeLEON (*DAUBERT* MOTION NO. 5)

I, Benjamin M. Greenblum, declare and state as follows:

1. I am a partner at the law firm of Williams & Connolly LLP. I represent AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. in the above-captioned matter. I am admitted *pro hac vice* in this Court. I have personal knowledge of the facts set forth herein, and if called as a witness, could and would testify to them.

2. Exhibit 4 is a true and correct copy of excerpts of the transcript of the March 1, 2024 deposition of Janet K. DeLeon.

Dated: October 7, 2024

By: */s/ Benjamin M. Greenblum*

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EXHIBIT 4

IN THE UNITES STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: SEROQUEL XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	))))	Master Docket No. 20-1076-CFC

VIDEOTAPED DEPOSITION OF JANET K. DeLEON, produced, sworn and examined on March 1, 2024, between the hours of 9:00 o'clock in the morning and 5:00 o'clock in the afternoon of that day, taken at the law offices of Sanders Warren & Russell, LLP, 11225 College Boulevard, Suite 450, Overland Park, Kansas, before Stacy L. Decker, a Certified Court Reporter (MO), Certified Shorthand Reporter (KS) in a certain cause now pending before the United States District Court for the District of Delaware, IN RE: Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation; taken on behalf of the Defendants.

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applications as ANDAs today?

A. Yes, that would be fine.

Q. Ms. DeLeon, you are not, however, an expert in the physical properties of hydroxypropyl methyl cellulose, correct?

A. I am not, no.

Q. You are also not an expert in the physical properties of methyl cellulose, correct?

A. Correct.

Q. You are not an expert in the gelation properties of hydrogenated vegetable oil, correct?

A. I am not, no.

Q. And you are not an expert in selecting which excipients to include in a pharmaceutical formulation, correct?

A. Correct. That's not part of my assignment today.

Q. That's what I figured and I just want to make sure I understand the full scope of your assignment.

You're also not an expert in the design of pharmaceutical formulations, correct?

A. I have developed many formulations

and gained approval for those products over the years, but my true expertise is in regulatory.

Q. Ms. DeLeon, you are not an expert in the design of the milling process that creates the particles of an active pharmaceutical ingredient, correct?

A. No, I'm not an expert in that.

Q. And you are not an expert in troubleshooting the curing processes for an extended release tablet, correct?

A. Correct.

Q. So you are not an expert in the manufacture of the pharmaceutical formulation as opposed to the regulatory approval of the pharmaceutical formulation, correct?

A. I would not say that I'm an expert in that. However, I've sat on many cross-functional teams for over 36 years, and so I'm very familiar with it. Of course, I'm not a pharmacist and never went through the formal training that pharmacists do in order to become a formulator.

Q. Ms. DeLeon, you are not an expert in providing comprehensive oversight for a multiple line pharmaceutical manufacturing

facility, correct?

A. I have never been the management of one of those facilities, no. But, again, I've worked on many cross-functional teams that employ exactly that. So I'm very familiar with it.

Q. Ms. DeLeon, are you an expert in the negotiation of raw materials supply contracts?

A. I'm not a purchaser is what we call it. The purchasing department does that. But, again, I'm very familiar with the process. I've been on multiple cross-functional teams that employ that. I myself have -- when I was at Cypress Pharmaceutical, I participated in purchasing those excipients and raw materials in general as well as the components that go into drug products. So I'm very familiar with it, but it's -- that -- that is mainly my expertise.

Q. It was not your day job; it was something your colleagues did that you heard about; is that fair?

A. Exactly, yes. I would participate on a team and we would discuss it regularly.

(Exhibit 360 was marked.)

Q. (By Mr. Fletcher) I'm now marking as Exhibit 360 a document. Ms. DeLeon, what is Exhibit 360?

A. It's my resume.

Q. Do you recognize it?

A. I do.

Q. Are there any changes to this resume since it was submitted as an exhibit to your opening expert report?

A. No. No changes, no.

Q. On the first page of the resume, you refer to your role as the chief executive officer of Jandel Pharmaceuticals. Do you see that?

A. I do.

Q. Has Jandel Pharmaceuticals ever marketed a product?

A. It has not.

Q. Has Jandel Pharmaceuticals ever sought regulatory approval for a product?

A. No, it has not. Jandel is a start-up company that we have looked into several different products to acquire or to develop and haven't quite gotten to the point where we've actually gotten a product on hand,

so it still remains a start-up company.

Q. A start-up where you are looking to in-license a drug to develop; is that correct?

A. Possibly. Currently we're looking at ACell therapy, that is with a university, and we're -- we've got terms in place, but we're looking for investors.

Q. Is the name Jandel Pharmaceuticals just a truncation of Janet DeLeon?

A. It is, yes.

Q. How many employees does Jandel Pharmaceuticals have?

A. Two at this point.

Q. And who are the employees?

A. Myself and Rob Lewis.

Q. And what is Rob Lewis' role?

A. He is the co-founder. He is an expert at developing products and companies. He is very familiar with the financial end of the business. He was my boss when I was at Cypress Pharmaceutical. So we've worked together many years. Seven years at Cypress, as well as the past ten years he and I have both run our consulting companies and have interacted on

multiple products. We're very familiar with each other.

Q. Did Jandel Pharmaceuticals have any revenue in 2023?

A. It did not, no.

Q. Has Jandel Pharmaceuticals ever had any revenue?

A. No. We're actually at a negative right now.

Q. Staying on the first page of your resume, Exhibit 360, in the bullets under the highlights you indicate that you have been responsible for approval of 12 NDAs and ANDAs in six and a half years. Do you see that?

A. I do.

Q. How many of those 12 were ANDAs to the best of your memory?

A. I believe it was nine of them.

Q. And so three were NDAs to the best of your memory?

A. Yes.

Q. The distinction between an NDA and an ANDA is an NDA is a new drug application, whereas, the ANDA is the abbreviated new drug application, correct?

Q. In your answer there you're referring to the active pharmaceutical ingredient; is that correct?

A. It is, yes, otherwise called API or drug substance.

Q. Hetero did not make the actual tablets; it provided the API to Accord for Accord to make into tablets; is that fair?

A. That is fair, yes.

Q. So when you say Hetero could have supplied the XR product, too, you mean Hetero could have provided the quetiapine fumarate for the XR product?

A. Yes. Thank you for that correction, yes.

Q. You also -- have you analyzed the Accord manufacturing process for the extended release tablets?

A. Not in particular, no. But I am familiar with other XR products.

Q. From your prior work experience?

A. Exactly, yes.

Q. Have you studied the manufacturing process for any XR product specific to this case?

A. Not the specific procedure, no. No.

Q. You mentioned that both the IR and XR tablets are extremely similar. Did I get that correct?

A. I did, uh-huh.

Q. They both use the exact same active pharmaceutical ingredient; is that right?

A. That's right.

Q. And in the case of Accord, the active pharmaceutical ingredient for both the Seroquel IR tablets and Seroquel XR tablets even came from the same supplier; is that correct?

A. That's correct as I understand it, yes.

(Exhibit 361 was marked.)

Q. (By Mr. Fletcher) Ms. DeLeon, I'll hand you what I've marked as Exhibit 361.

A. Okay.

Q. Ms. DeLeon, what is Exhibit 361?

A. It's a list of documents that I relied on for my report.

Q. And that is, in fact, the title of the document is "List of Documents Relied Upon"; is that right?

Q. But you were not asked to, correct?

A. Correct.

Q. Ms. DeLeon, how did you go about preparing your report, Exhibit 359?

MS. HASS: Objection. Ms. DeLeon, I just want to caution you to not reveal any attorney communications that you didn't rely on like your assignment and anything about the drafting process, which is privileged and confidential.

THE DEPONENT: Okay.

A. So I was provided an assignment, which I stated earlier was the impediments to regulatory approval or impediments to launching the XR generic product for Accord. And so I requested documents that would support or negate that. Either way, I analyzed anything that was available and put together this report based on the findings that I saw in the documentation.

Q. (By Mr. Fletcher) Ms. DeLeon, do you have an estimate for how many hours you spent preparing this report?

A. I do not, no. I'm sorry.

Q. Did you review the report for

accuracy before you signed it?

A. Of course.

Q. Did you proofread the report?

A. I definitely did, which I'm glad you brought that up. I did find one error that I'd like to bring up.

Q. Sure.

A. It's actually on Paragraph 39.

Q. Okay.

A. I apologize that I didn't bring this up earlier.

Q. What would you like to correct in Paragraph 39?

A. Let me make sure that it is 39 to begin with. It would be on the third line. And it says, "indicating that an ANDA holder does seek approval of its generic product." And it should be "does not." Okay. I missed the word "not" in that. Sorry.

Q. That's okay. I think we understood what you were trying to say. But I've made the note for myself, Paragraph 39, third line, ANDA holder does not seek approval.

A. For Paragraph 3, yes.

Q. Okay. And you noticed this as

part of your preparation for today's deposition?

A. I did, yes.

Q. So you've reviewed this report for accuracy when you signed it and again as part of your preparation for this deposition, correct?

A. Correct, yes.

Q. At least twice then?

A. At least, yes.

Q. Or were there more than two reviews for accuracy?

A. Yes. Yes.

Q. Can you describe your process for making sure that the report accurately reflects your views, like how many times?

A. How many times I reviewed again or --

Q. Or how did you make sure that it reflected your views accurately?

A. Well, I would -- I read through the report. I checked all of the references in there. I also relied on my historical knowledge over 36 years, experiences that I've had in the industry, working for small, medium, and large companies. I put my wealth of experience into it. But I also looked at the documentation that

was provided. I also looked at some other documents that were not referenced in the report just to make sure I didn't miss something.

Q. Like the guidance, is that what you're referring to?

A. Which guidance?

Q. Sorry. When you say you looked at other documents not referenced in the report, are you referring to those FDA guidance, ICH concepts that are just --

A. Yes, exactly.

Q. Anything else?

A. No. It would be those, those guidances.

Q. So when you cited a document or a reference, you checked to make sure it said what you were characterizing it as in your report; is that fair?

A. Yes, I did.

Q. So I'd like to go back to the very first page of the report to just understand something.

A. Okay.

Q. Very second -- second paragraph, heading two. Ms. DeLeon, what does heading two

refer to?

A. It says jurisdiction and venue.

Q. What is jurisdiction?

A. The parameters which I am working within.

Q. Okay. And what is venue?

A. Again, I believe it's a legal term, but it's -- it's the part that I'm working within.

Q. So what follows in paragraphs 2 through 17 is your professional background, right?

A. Yes, it is. Uh-huh.

Q. And you described your professional background as your jurisdiction and venue; is that right?

A. That's what it is, yes.

Q. That's not a typo, right?

MS. HASS: Objection, asked and answered.

A. Yeah, it -- this is -- this is what I've written.

Q. (By Mr. Fletcher) Okay. Just we were correcting typos before. We corrected Paragraph 39. We don't need to correct heading

two, though, correct?

A. I don't believe so. I'm not a lawyer. Legal terms sometimes are misused by me, I'll admit, but I believe that these are correct.

Q. So only one typo and it's in Paragraph 39?

A. Yes.

Q. Okay. Paragraph 62, if you could please go to that paragraph again.

A. 62?

Q. Yes. Paragraph 62, you refer to NDA number 022047. Do you see that?

A. I do.

Q. And what was NDA 022047?

A. It was the branded version from AstraZeneca for the Seroquel XR.

Q. And pursuant to NDA number 022047, FDA gave approval to AstraZeneca to sell the 50, 150, 200, 300, and 400 milligram strengths, correct?

A. Correct.

Q. And in Paragraph 63 you describe Accord's ANDA, correct?

A. Yes, I do.

Q. How is a capsule different from a tablet?

MS. HASS: Objection. Outside the scope of her report.

A. It's not something I was asked to opine on.

Q. (By Mr. Fletcher) In your experience is a capsule different from a tablet?

MS. HASS: Same objection.

A. So I wasn't asked to opine on that.

Q. (By Mr. Fletcher) Okay. The flow chart reflects that capsules go through an encapsulation process, correct?

A. Yes.

Q. [redacted]

MS. HASS: Same objection. Outside the scope of her report.

A. I wasn't asked to opine on that.

Q. (By Mr. Fletcher) Okay. You analyzed this document as part of your report, correct?

A. This document, yes, in general.

Q. As part of your understanding about impediments to launch, correct?
A. Yes.
Q. The third column such as it is on slide 63481 refers to pellets, correct?
A. Yes.
Q. What is a pellet?
A. A pellet is typically something that goes into a capsule.
Q. The fourth column refers to effervescent tablets. Do you see that?
A. I do.
Q. What is an effervescent tablet?
MS. HASS: Objection. Outside the scope of her report.
A. I wasn't asked to opine on that.
Q. (By Mr. Fletcher) Have you ever worked on an effervescent tablet before?
A. I have not, no.
Q. Do you think Alka-Seltzer is an effervescent tablet?
A. It is.
MS. HASS: Objection.
Q. (By Mr. Fletcher) So you have some familiarity with effervescent tablets?

A. Some, yes.
Q. Column five, what is a narrow therapeutic tab?
MS. HASS: Same objection. Outside the scope of her report.
A. I wasn't asked to opine on that.
Q. (By Mr. Fletcher) Do you know what that is?
A. In general.
Q. What -- in general what does it mean?
MS. HASS: Same objection.
A. It's a product that has a vast difference in biologic profile.
Q. (By Mr. Fletcher) If we turn to the next slide, we have -- the slide is entitled "Oral Solids Capacities," correct?
A. Yes.
Q. And the first column is dosage form; is that right?
A. It is.
Q. And the second column is annual capacity, correct?
A. Yes.
Q. And as you understand this table,

the annual capacity column refers back to the corresponding dosage form in the column on the left, correct?

A. I would assume so since it's all within the same section of the slide deck.

Q. [redacted]

MS. HASS: Objection to form.

A. So that's what is here on the document. I'm not exactly sure if this is accurate or not, as with the other ones. All I can do is read what's here on the page.

Q. (By Mr. Fletcher) Okay. What would you need to know to confirm whether this is an accurate annual capacity? How would you do that?

A. Typically I would ask the people who run the manufacturing facility what their capacity is as of today. This document -- I don't know the date on it. It could have been five years old at the time.

Q. Okay. As you understand this document, which was the second document listed in your materials relied upon, [redacted], correct?

A. I see that.

Q. And that's the correct way to read this document?

A. I believe so. I -- I've never worked with INTAS, so I don't know their exact meaning. But from an outsider perspective, I think that would be something that could be concluded.

Q. So now if we can keep that open, but if we can turn back to your report, paragraph 156. This is a document that you

cited in your analysis in paragraph 156, correct?

A. Yes.

Q. And specifically this slide that we were just looking at is what you cited in support of your footnote 176, correct?

A. Yes.

Q. And in your analysis you concluded that [redacted]. Do you see that?

A. I do see that.

Q. Would it be more fair to say that [redacted]?

A. So according to this document here, that's what it says, yes.

Q. Okay. This document that you've cited does not separately identify the annual capacity at [redacted] for making tablets, correct?

A. Correct.

Q. And do you know what [redacted] annual capacity was for making tablets?

A. Off the top of my head, no. I had to rely on this document.

Q. Okay. And you're not aware of any

document other than this slide 482 that informs the annual capacity for tablets at [redacted], correct?

A. This is the document that I referenced.

Q. So sitting here today -- well, I think we can move on.

In paragraph 155, you describe Accord as one of the fastest growing U.S. generic companies; is that correct?

A. So here it says, "In early 2015 INTAS, Accord's Indian parent company, described itself," excuse me, "as one of the fastest growing Indian pharmaceutical companies."

Q. And, sorry, I was on the prior sentence.

A. Yes. Okay. It does say Accord was one of the fastest growing U.S. generic companies.

Q. How does that statement factor into your analysis?

A. It factors into my analysis because I have worked with similar companies that were trying very hard to grow fast. I've worked with small, medium, and large companies

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on October 7, 2024 on the following counsel in the manner indicated below.

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DATED: October 7, 2024

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